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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/662,000	09/12/2003	Andrzej J. Chanduszko	106586.185US1	8600

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EXAMINER	
POUS, NATALIE R	
ART UNIT	PAPER NUMBER
3731	

SHORTENED STATUTORY PERIOD OF RESPONSE	NOTIFICATION DATE	DELIVERY MODE
3 MONTHS	02/20/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 02/20/2007.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/662,000	CHANDUSZKO, ANDRZEJ J.	
	Examiner	Art Unit	
	Natalie Pous	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-38 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-38 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :1/21/05, 2/28/05, 5/1/06, 6/28/04.

DETAILED ACTION

Response to Arguments

Regarding Huebsch

Applicant's arguments with respect to claims 1-35 have been considered but are moot in view of the new ground(s) of rejection based on amendments to the claims.

Regarding Sideris

Applicant's arguments with respect to claims 1-3, 5-7, 19-24, 29 and 34-38 have been considered but are moot in view of the new ground(s) of rejection based on amendments to the claims. With regards to the limitation wherein the center joint is attached to at least one of the members at a side of the members in the same manner as that of the application, examiner asserts that Sideris teaches this limitation in the same manner as taught by the applicant. That meaning that in the embodiment of the present application, figs 25-51, the center joint is not directly attached to the cylindrical members, instead it is attached to scaffold 260 which is attached to the cylindrical members. In the same manner, the center joint of Sideris is attached to the members via scaffold members 40.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 20 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships are: the scaffold which attaches the center joint to the cylindrical member. Without the scaffold member, the specification is not enabling, as the embodiment of the present application requires that the center joint be located in the gap created by the split of the cylindrical members.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-10, 12, 15-23, 26-32 and 34-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sideris (US 5284488) in view of Huebsch et al. (US 5853422) as a matter of design choice.

Sideris teaches a device for closing a defect in septal tissue comprising the following:

- a first side (34) adapted to be disposed on one side of the septal tissue
- a second side (38) adapted to be disposed on the opposite side of the septal tissue
- said first and second sides connected by a at least one center joint (42), wherein each of said first and second sides includes an anchor member (34, 38) having an elongate oval shape (column 5 proximate lines 25-30
- and wherein said first and second sides cooperate to provide a compressive force to the septal tissue surrounding the defect when said device is deployed at an intended delivery location (Column 3, proximate lines 30-43).
- a retrieval mechanism (18, 44) for retrieving said device from its intended delivery location.
- said retrieval mechanism reduces the profile of said device such that said device may drawn into a catheter (fig. 4).
- said retrieval mechanism reduces the distance between said first and second anchor members and aligns said first and second anchor members in a longitudinal orientation (fig. 4).

- said retrieval mechanism comprises a string extending from one end of said first anchor member to and through said second anchor member (44), and a ball constrained on said string within said second anchor member (connection of string 44 to skeleton wire 40). It is noted that according to Merriam Webster, the definition of ball is as follows: a round or roundish body or mass. Further, the knot or tie at the connection of the string 44 to skeleton wire 40 is roundish.
- said string (44) is flexible. It is noted that string (44) is comprised of nylon thread, which is inherently flexible.
- the center joint (42) extends through the defect in the septal tissue when said device is deployed at its intended delivery location.
- wherein said first and second anchor members (34, 38) are three-dimensional.
- anchor members include a material selected from the group consisting of metals, polymers, shape memory materials, bioresorbable materials, drug-exuding materials, and combinations of the foregoing materials (Column 4, proximate lines 40-43).
- at least one center joint includes a stretchable elastomeric material (Column 3, proximate lines 1-6).
- each of said anchor members (34, 38) is configured to minimize the septal profile of said device.
- each of the first and second anchor members includes a tissue scaffold (40)
- wherein each center joint is connected to the tissue scaffold (fig. 3)

Sideris fails to teach the following:

- anchors comprising a generally cylindrical member split along the central portion of its length.
- wherein said at least one center joint includes a shape memory material
- wherein said at least one center joint includes nitinol
- wherein said at least one center joint comprises a nitinol film
- wherein said at least one center joint includes a material that promotes closure of the defect in the septal tissue
- wherein said tissue scaffold includes a material selected from the group consisting of polyester fabrics, Teflon-based materials, ePTFE, polyurethanes, metallic materials, polyvinyl alcohol (PVA), extracellular matrix (ECM), synthetic bioabsorbable polymeric scaffolds, collagen, drug-exuding materials, and combinations of the foregoing materials

Regarding the limitation wherein the anchor member comprises at generally cylindrical member split along a central portion of its length to form an elongate ova, Huebsch teaches a device for closing a defect in septal tissue wherein the anchor member comprises at generally cylindrical member split along a central portion of its length to form an elongate oval. It would have been an obvious matter of design choice to form the anchor members from generally cylindrical members split along the center portion of their length, since applicant has not disclosed that such a configuration provides any advantage over the configuration of Sideris, and it appears the anchor

members of Sideris perform the task of increasing the size and surface area of the anchor member, thereby improving the dislodgement resistance of the closure device equally well as that disclosed in the application.

Regarding the limitation wherein said at least one center joint includes a shape memory material such as Nitinol, Huebsch teaches wherein the device is formed of Nitinol in order to provide a device that does not rely on mechanical forces for deformation to its deployed shape. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Sideris with Nitinol in order to provide a device that does not rely on mechanical forces for deformation to its deployed shape, and use of such material is well known in the art.

Regarding the limitation wherein the center joint includes a material that promotes closure of the defect in the septal tissue, Huebsch teaches wherein the center joint includes a material that promotes closure of the defect in the septal tissue in order to allow ingrowth to help in the stabilization of the device (Column 7, proximate lines 44-56). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Sideris with the center joint including a material that promotes closure of the defect in the septal tissue in order to allow ingrowth to help in the stabilization of the device.

Regarding the limitation wherein said tissue scaffold includes a material selected from the group consisting of polyester fabrics, Teflon-based materials, ePTFE, polyurethanes, metallic materials, polyvinyl alcohol (PVA), extracellular matrix (ECM), synthetic bioabsorbable polymeric scaffolds, collagen, drug-exuding materials, and

combinations of the foregoing materials, Huebsch teaches wherein the device may include material from this group (Column 2, proximate lines 37-40). It would have been obvious to one of ordinary skill in the art at the time the invention was made to denote the tissue scaffold as being made of one of the disclosed materials since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

Claims 13 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Sideris and Huebsch and further in view of Hannam (US 5649959). The combination of Sideris and Huebsch teaches all aspects of preceding dependent claims as previously described, fails to disclose using glue, thrombogenic materials, or growth factors to accelerate tissue ingrowth, but Hannam discloses a similar anchor member 30 (see Fig. 12) and teaches injecting such materials (fibrin glue, cyanoacrylate, etc.) (column 8 lines 32-47) in conjunction with plug 30 in order to form a blood clot more quickly and allow the tissue to heal more quickly. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to apply fibrin glue to the combination of Sideris and Huebsch in order to more rapidly form a blood clot.
as taught by Hannam.

Claims 11 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Sideris and Huebsch, and further in view of Kanesaka et al (US 5776183). The combination of Sideris and Huebsch teaches all aspects of preceding

dependent claims 1 and 7, but fails to disclose wherein said at least one center joint is porous or comprises holes. Kanesaka teaches a medical prosthesis comprising pores to absorb or retain a drug for slow release. It would have been obvious to on one of ordinary skill in the art at the time the invention was made to modify the device of the combination of Sideris and Huebsch with a porous material as taught by Kanesaka in order to slowly release a drug into the tissue.

Claims 24-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Sideris and Huebsch, and further in view of Simon (US 5741297). The combination of Sideris and Huebsch teaches all aspects of preceding claims 20-23 as previously described, but fails to disclose wherein the arcs of the member are positioned at an angle from the plane of the device orthogonal to the axis of the center joint, the anchor members being is concave in shape, or where the angle θ is greater than 0 degrees and less than about 45 degrees. Simon teaches a device for closing a septal defect wherein the device generally concave, and the end of the device is offset from the center plane at an angle greater than 0 degrees and less than about 45 degrees in order to engage and corrugate the septum to hold the occluder in place. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Sideris and Huebsch as taught by Simon in order to engage and corrugate the septum to hold the occluder in place.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalie Pous whose telephone number is (571) 272-6140. The examiner can normally be reached on Monday-Friday 8:00am-5:30pm, off every 2nd Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NRP
2/6/07

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2/6/07